

CLAIMS

What is claimed is:

1. A dilator and sheath assembly comprising:

a) a dilator having:

- 1) an elongated dilator stem having a proximal dilator end; and
- 2) a dilator hub fixedly connected to the proximal dilator end, wherein the dilator hub includes a threaded portion at a distal portion thereof;

and

b) a sheath having:

- 1) an elongated tubular portion having a proximal sheath end, a distal sheath end, and a longitudinal axis extending between the proximal sheath end and the distal sheath end, wherein the tubular portion is sized to frictionally retain the dilator stem;
- 2) at least one tear seam extending in a plane between the proximal sheath end and the distal sheath end; and
- 3) a sheath hub fixedly connected to the proximal sheath end, wherein the sheath hub includes a proximal portion and a mating threaded portion at a proximal end thereof, wherein the threaded portion of the dilator hub and the mating threaded portion of the sheath hub provide a releasably locking engagement between the dilator and the sheath.

2. The dilator and sheath assembly according to claim 1, wherein the at least one tear seam comprises two tear seams located in the plane, wherein the plane longitudinally bisects the sheath.

3. The dilator and sheath assembly according to claim 2, wherein the sheath hub further comprises two opposing reveals disposed parallel to the longitudinal axis of the tubular portion, and wherein the opposing reveals are located in the plane including the at least one tear seam.
4. The dilator and sheath assembly according to claim 1, wherein the dilator hub further comprises one of a male and a female thread and the sheath hub comprises the other of the male and female thread so as to mate to the dilator hub to provide a releasably locking engagement between the dilator and the sheath.
5. The dilator and sheath assembly according to claim 1, wherein the sheath hub comprises a flush surface at the proximal portion thereof, wherein the flush surface is perpendicular to the longitudinal axis of the tubular sheath, wherein the flush surface is generally flat around an entire circumference of an opening in the sheath hub, and wherein the opening defines a proximal end of the tubular portion.
6. The dilator and sheath assembly according to claim 1, wherein the sheath hub comprises two opposing winged tabs, wherein each winged tab includes a perpendicular portion and an angled portion, wherein the perpendicular portion extends laterally from the sheath hub in a plane perpendicular to the longitudinal axis of the tubular portion, and wherein the angled portion of the winged tab extends from the perpendicular portion, wherein an angle between the perpendicular portion and the angled portion is between approximately 90° and approximately 179° .
7. The dilator and sheath assembly according to claim 6, wherein the angle is between approximately 130° and approximately 140° .
8. A dilator and sheath assembly comprising:
 - a) a dilator having:

- 1) an elongated dilator stem having a proximal dilator end; and
 - 2) a dilator hub fixedly connected to the proximal dilator end;
- b) a sheath having:
- 1) an elongated tubular portion having a longitudinal axis, a proximal sheath end and a distal sheath end, wherein the tubular portion is sized to frictionally retain the dilator stem;
 - 2) at least one tear seam extending in a plane between the proximal sheath end and the distal sheath end; and
 - 3) a sheath hub fixedly connected to the proximal sheath end;
- and
- c) a means for providing a releasably locking engagement between the distal portion of the dilator hub and the proximate portion of the sheath hub.
9. The dilator and sheath assembly according to claim 8, wherein the at least one tear seam comprises two tear seams located in the plane, wherein the plane longitudinally bisects the sheath.
10. The dilator and sheath assembly according to claim 9, wherein the sheath hub comprises two opposing reveals disposed parallel to the longitudinal axis of the elongated tubular portion and wherein the opposing reveals are located in the plane including the at least one tear seam.
11. The dilator and sheath assembly according to claim 8, wherein the sheath hub comprises a flush surface at the proximate portion thereof, wherein the flush surface is perpendicular to the longitudinal axis of the tubular sheath, wherein the flush surface is generally flat around an entire circumference of an opening in the sheath hub, and wherein the opening defines a proximal end to the elongated tubular portion.

12. The dilator and sheath assembly according to claim 8, wherein the sheath hub comprises two opposing winged tabs, wherein each winged tab includes a perpendicular portion and an angled portion, wherein the perpendicular portion extends laterally from the sheath hub in a plane perpendicular to the longitudinal axis of the tubular portion, and wherein the angled portion of the winged tab extends from the perpendicular portion, wherein an angle between the perpendicular portion and the angled portion is between approximately 90° and approximately 179°.
13. The dilator and sheath assembly according to claim 12, wherein the angle is between approximately 130° and approximately 140°.
14. A dilator and sheath assembly comprising:
- a) a dilator having an elongated dilator stem, a proximal dilator end and a dilator hub fixedly connected to the proximal dilator end, wherein the dilator hub includes a threaded portion at a distal portion thereof; and
 - b) a sheath having:
 - (i) a proximal sheath end, a distal sheath end and an elongated tubular portion having a longitudinal axis extending between the proximal sheath end and the distal sheath end;
 - (ii) two tear seams extending along the tubular portion between the proximal sheath end and the distal sheath end, wherein the two tear seams are located on opposite sides of the sheath and are in a plane containing the longitudinal axis of the sheath; and
 - (iii) a first and second opposing sheath hub portions, wherein each of the first and second sheath hub portions comprise an inverted semicircular edge fixedly connected to the sheath, whereby the first and second sheath hub portions generally encircle the

tubular sheath and whereby there are small spaces between the first and second sheath hub portions, wherein the spaces between the first and second sheath hub portions are aligned with the two tear seams on the sheath; wherein each of the first and second sheath hub portions comprise a threaded portion at a proximal end thereof, whereby the first and second threaded portions form a circular threaded portion forming the proximal end of the sheath, and whereby the threaded portion is matable with the threaded portion of the dilator hub to provide a releasably locking engagement between the dilator and the sheath.

15. The dilator and sheath assembly according to claim 14, wherein the dilator hub includes one of a male and a female thread and the sheath hub includes the other of the male and female thread so as to mate to the dilator to provide a releasably locking device to attach the dilator to the sheath.
16. The dilator and sheath assembly according to claim 14, wherein the first and second opposing sheath hub portions are connected to each other on either side of the longitudinal axis by at least one web on opposing sides of the longitudinal axis, wherein the at least one web constitutes a weakened portion in the sheath hub, bonded to the sheath hub portions to form a complete circle around the sheath, wherein the at least one web has a tensile strength less than that of the sheath hub.
17. The dilator and sheath assembly according to claim 16, wherein the at least one web is positioned along a proximal opening in the sheath hub, whereby the at least one web and the two sheath hub portions form a flush top surface, wherein the flush top surface is generally flat, wherein the flush top surface is perpendicular to the longitudinal axis of the sheath, and wherein the flush top surface defines a proximal end in the tubular portion.

18. The dilator and sheath assembly according to claim 14, wherein the first and second opposing sheath hub portions are connected on either side of the longitudinal axis by a member on each side, wherein the member is bonded to the hubs to form a complete circle around the sheath, wherein the member is of a tensile strength less than that of the sheath hub portions so as to assist in the splitting of the sheath and separation of the sheath along the plane containing the axis of the sheath and the two tear seams.
19. A method of separating a dilator from a sheath comprising:
- a. providing a dilator having a dilator stem extending along a longitudinal axis and a dilator hub connected to a proximal end of the dilator stem, wherein the dilator hub comprises a male threaded portion;
 - b. providing a sheath having a sheath hub comprising a female threaded portion and winged tabs having a perpendicular portion and an angled portion, whereby the dilator is releasably connected to the sheath by mating the threads on the dilator hub to the threads on the sheath hub;
 - c. rotating the dilator around the longitudinal axis in relation to the sheath, thereby unthreading the male threaded portion from the female threaded portion; and
 - d. disengaging the dilator from the sheath.
20. The method according to claim 19, wherein the dilator further comprises a distal tip and a hollow passageway extending along the longitudinal axis, wherein the method, prior to step (c), further comprises:
- a. providing a needle having a hollow tip, and providing a guide wire having a proximal end;
 - b. probing the area to be catheterized;

- c. making an incision near a vessel to be catheterized;
 - d. inserting the needle into the vessel to be catheterized;
 - e. inserting the guide wire through the hollow tip of the needle into the vessel to be catheterized;
 - f. removing the needle by sliding the needle longitudinally and proximally along the guide wire while leaving the guide wire inside of the vessel to be catheterized;
 - g. inserting the dilator and sheath into the vessel by inserting the proximal end of the guidewire into the hollow passageway in the distal tip of the dilator and sliding the hollow dilator and sheath along the guide wire until the tip of the dilator is inserted into the area to be catheterized; and
 - h. removing the guidewire from the patient.
21. The method according to claim 19, wherein the sheath further comprises (i) a hollow passageway along the longitudinal axis of the sheath, (ii) a proximal portion with a proximal tip having an opening at the proximal end thereof, and (iii) a distal portion having a distal tip having an opening at the distal end thereof, wherein the method further comprises, after step (d), sliding the dilator in a proximal direction along the longitudinal axis in relation to the sheath until the dilator is removed from the sheath.
22. The method according to claim 21, further comprising, upon removal of the dilator from the sheath, inserting a capping device in the proximal end of the sheath hub
23. The method according to claim 21, wherein the sheath further comprises (i) a plurality of tear seams running the length of the sheath and being situated on a plane bisecting the sheath through the longitudinal axis, and (ii) a sheath hub located at a proximal portion of the sheath, the sheath hub having two opposing reveals running parallel to the longitudinal axis of the

sheath and being located in a plane including the tear seams and the longitudinal axis of the sheath and two opposing winged tabs, wherein each winged tab includes a perpendicular portion having a proximal surface and an angled portion, wherein the perpendicular portion extends laterally from the sheath hub in a plane perpendicular to the plane containing the longitudinal axis of the sheath and the two opposing reveals and the angled portion of the tab extending from the perpendicular portion, wherein an angle between the proximal surface of the perpendicular portion and the angled portion is between 90° and 179° ; wherein the method further comprises:

- a. providing a catheter assembly having a distal tip, a proximal region, and a longitudinal tubular portion extending between the distal tip and the proximal region;
- b. inserting the distal tip of the catheter assembly into the opening at the proximal end of the sheath;
- c. inserting the catheter assembly longitudinally through the sheath until the distal tip of the catheter is in the area to be catheterized;
- d. removing the sheath from around the inserted catheter assembly by simultaneously pulling the sheath in a proximal direction while grasping the sheath hub by the winged tabs and pulling the winged tabs away from each other while applying a distal force to the proximal surface of the angled portion of the tab and a proximal force to the distal surface of the perpendicular portion of the tab thereby tearing the sheath along the tear seams;
- e. pulling the sheath halves proximally over the catheter while leaving the catheter assembly in such a place that the distal tip of the catheter is at the place to be catheterized; and
- f. closing the wound around the catheter.

24. The method of separating the dilator from the sheath according to claim 19, wherein step (c) comprises rotating the dilator approximately 90° around the longitudinal axis in relation to the sheath.
25. A method of removing a sheath from around a catheter assembly, wherein the catheter assembly and sheath are both partially disposed inside of a desired vessel to be catheterized, the sheath having:
- a. a longitudinal axis;
 - b. a distal portion having a distal tip with a hollow portion aligned with the longitudinal axis of the sheath;
 - c. an elongated tubular structure comprising a hollow passageway traversing the entire longitudinal axis of the sheath;
 - d. a proximal portion comprising a proximal tip at the proximal end thereof and a hollow passageway along the longitudinal axis of the sheath;
 - e. two opposing tear seams running entire length of the sheath and coplanar with the longitudinal axis of the sheath; and
 - f. a sheath hub fixedly connected to the proximal portion of the sheath, the sheath hub comprising:
 - (i.) two opposing reveals disposed parallel to the longitudinal axis of the tubular sheath and are coplanar with the tear seams running along the surface of the sheath and the longitudinal axis of the sheath; and
 - (ii.) two opposing winged tabs, each tab includes a perpendicular portion and an angled portion, the perpendicular portion extending laterally from the sheath hub in a plane perpendicular to the plane containing the longitudinal axis of the sheath

and the two opposing reveals and the angled portion of the tab extending from the perpendicular portion, wherein an angle between the proximal surface of the perpendicular portion and the angled portion is between 90° and 179°;

the method comprising:

- A. applying a distal force to the proximal surface of the angled portion of each of the winged tabs;
 - B. applying a proximal force to the distal surface of each of the tabs at a point on the tab closer to the center of the sheath than the point upon which the distal force is applied to the proximal surface;
 - C. grasping the tabs of the sheath and pulling them outward from the center of the sheath thereby separating the sheath into two halves along the tear seams running the length of the sheath; and
 - D. pulling the sheath in a proximal direction.
26. The method according to claim 25 whereby steps (A), (B), (C), and (D) are performed generally simultaneously, while leaving the catheter assembly in place.